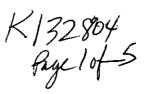
Siemens Medical Solutions, Inc. **Ultrasound Division** 

S-Family Ultrasound Systems 510(k) Submission



## 510(k) Summary Prepared July 18, 2013

1. Sponsor:

Siemens Medical Solutions, Inc.,

Ultrasound Division

685 East Middlefield Road

Mountain View, California 94043

OCT 2 4 2013

Contact Person:

Christine Dunn

Telephone:

(425) 785-1617

Fax:

(425) 391-9161

2. Device Name:

Acuson S1000, S2000, S3000™ Diagnostic Ultrasound Systems.

Common Name:

Diagnostic Ultrasound System

Classification:

Regulatory Class:

11

Review Category:

Tier II

Classification Panel: Radiology

Ultrasonic Pulsed Doppler Imaging System FR # 892.1550 Ultrasonic Pulsed Echo Imaging System

FR # 892.1560

Product Code 90-IYN Product Code 90-IYO

Diagnostic Ultrasound Transducer

FR # 892.1570

Product Code 90-ITX

Diagnostic Ultrasound Catheter

FR # 870.1200

Product Code OBJ

#### 3. Legally Marketed Predicate Devices

The modified Acuson S1000, S2000, S3000 Ultrasound Systems are substantially equivalent to the company's own systems:

System	510(k)
S1000	K130619; K123622; K123001
S2000	K130739; K112596; K123622; K123001
S3000	K130739; K121138; K123622; K123001

#### 4. Device Description:

The ultrasound systems are multi-purpose mobile, software controlled diagnostic ultrasound systems with and onscreen display for thermal and mechanical indices related to potential bio-effect mechanisms. The function is to acquire primary or secondary harmonic ultrasound echo data and display it in B-Mode, M-Mode, Pulsed (PW) Doppler Mode, Continuous (CW) Doppler Mode, Color Doppler Mode, Amplitude Doppler Mode, a combination of modes, or Harmonic Imaging and 3D/4D Imaging on a Flat Panel Display.

# 5. Intended Use

The ultrasound imaging systems are intended for the following applications: Fetal, Abdominal, Intraoperative, Pediatric, Small Parts, Transcranial, OB/GYN, Cardiac, Pelvic, Neonatal/Adult Cephalic, Vascular, Musculoskeletal, Superficial Musculoskeletal, and Peripheral Vascular applications.

The system also provides the ability to measure anatomical structures (fetal, abdominal, intraoperative, pediatric, small organ, neonatal cephalic, adult cephalic, cardiac, trans-esophageal, transrectal, transvaginal, peripheral vessel, musculo-skeletal (conventional), musculo-skeletal (superficial) and neonatal cardiac) and calculation packages that provide information to the clinician that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes.

The Arterial Health Package (AHP) software provides the physician with the capability to measure Intima Media Thickness and the option to reference normative tables that have been validated and published in peer-reviewed studies. The information is intended to provide the physician with an easily understood tool for communicating with patients regarding state of their cardiovascular system. This feature should be utilized according to the "ASE Consensus Statement; Use of Carotid Ultrasound to Identify Subclinical Vascular Disease and Evaluate Cardiovascular Disease Risk: A Consensus Statement from the American Association of Echocardiography; Carotid Intima-Media Thickness Task Force, Endorsed by the Society for Vascular Imaging".

The Acuson Acunav Ultrasound Catheter is intended for intra-cardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology, as well as visualization of other devices in the heart of adult and pediatric patients.

## 6. Summary of Technological Characteristics - New Device Compared to Predicate

Feature / Characteristic	Acuson S1000/S2000 /S3000 This Submission	Acuson SC2000 K123622	Acuson \$1000 K130619	Acuson \$2000 K112596	Acuson \$2000 K130739	Acuson \$3000 K121138	Acuson \$3000 K130739
Indications for Use:						· · · · · · · · · · · · · · · · · · ·	
■ Fetal	- √	4	٧	٧ -	٧ -	١ ٧	٧
<ul> <li>Abdominal</li> </ul>	√	1	1	₹	4	٧	- √
<ul> <li>Intraoperative</li> </ul>	√	4	4	<b>√</b>	✓	√ √	۷
Intraoperative neurological	[			]			•
Pediatric	√ i	<b>√</b>	4	[ √	1	√	٧
Small Organ	√	4	1	✓	\ √	<b>√</b>	1
Neonatal cephalic	√ V	1	4	٧ -	√	<b>√</b>	√
Adult Cephalic	٧	1	4	٧	٧ ا	<b>√</b>	√
Cardiac	√i	√	√	√ √	√	<b>√</b>	٧
■ Trans-esophageal	<b> </b>	4	4	4	٧	1	4
Transrectal	1 1	√	1	✓	✓	✓	1
Transvaginal	٧	4	4	√	√ `	√	√
Peripheral vessel	٧	٧	√	✓	٧	√ √	1
Laparoscopic			_		-	-	-
Musculo-sketetal (conventional)	<b>1</b>	1	✓	√	✓	٧	4
Musculo-skeletal (superficial)	<b>√</b>	V	4	٧	1	₹	٧
Center Frequencies Supported:							
2.0 MHz	1	√	1	√	√	√	✓
■ 3 0 MHz	1 1	√,	1	√	۷ √	√	٧
3 2 MHz		v <sup>i</sup>	√	4	√ √	√	4
3,3 MHz	1	√	٧	√ √	√	٧ -	√
4.2 MHz	√	√.	1	√	√	√	1
4 4 MHz	1	√.	V	<b>V</b>	✓	١ ٧	√

Feature / Characteristic	Acuson S1000/S2000 /S3000 This Submission	Acuson SC2000 K123622	Acuson \$1000 K130619	Acuson \$2000 K112596	Acuson \$2000 K130739	Acuson S3000 K121138	Acuson \$3000 K130739
■ 4.8 MHz		V	<b>√</b>	1	<b>V</b>	V	1
5.0 MHz	√	1	√	√	[ ✓	√	4
5.2 MHz	1	√.	✓	٧ -	Į v	₹	4 .
■ 6.0 MHz	1	<b>√</b>	4	√	٧.	√	٧
6.5 MHz	🗸	V	1	٧	\	V	٧
6.9 MHz	🗸	<b>V</b>	√	√	V	√	√
9.5 MHz	4	<b>V</b>	√	√ √	₹ 2	√	٧
10.0 MHz	1	<b>√</b>	1	- √	1	√	٧
Aodes:		<del></del>	<u> </u>				
<b>■</b> B	1 1	<b>√</b>	1	1	l v	1	V
Parallel processing in 8 mode	] , [	<b>√</b>	1	1	1	٧ .	٧
M		<b>√</b>	1	1	1	√	1
PWD (Pulsed Wave Doppler)		V	1	√	1	- √	1
CWD (Continuous Wave Doppler)	,	٧	1	V	1	1	1
D (Color Doppler)		V	1	V	l į	,	1
		J	l j	j	J	J	,
Ampikade Doppier		, V	;	į	;	j	j
Combined (BMDC)	· · ·	•		<u> </u>	<del></del>	<del> </del>	· · · · ·
	1	<b>V</b>	1	1	<del></del>	<del></del>	J
Quad processing in color	'	,		,	,		
Native™ tissue harmonic imaging		4	1	√	\ \	4	1
<ul> <li>SieScape™ panoramic imaging</li> </ul>	√	- √	1	1	1	<b>√</b>	٧
Cofor SieScape™ panoramic imaging	٧		٧	٧	٧	1	1
3-Scape ™ real-time 3D imaging			٧	<b>4</b>	4	٧	٧
fourSight™ 4D transducer technology	٧	· · · · · · · · · · · · · · · · · · ·	٧	<b>√</b>	٧	٧	٧
TEQ™ ultrasound technology	<b>V</b>	<b>√</b>	4	4	1	√	V
<ul> <li>Cardiac Imaging physiological signal display</li> </ul>	٧	٧	1	4	4	٧	1
syngo   Auto OB measurements	1		<u> </u>	1	√	√	√
Advanced SieClear™ spatial compounding	٧	√	٧	√	٧	٧	4
STIC (Fetal Heart Imaging)	٧		1	1	٧	<b>V</b>	1
Amnioscopic rendering	٧		٧	4	1	4	4
Cadence contrast agent imaging	V	V	4	٧	4	٧	1
Clarify™ vascular enhancement technology	٧ -	<b>V</b>	7	1	٧	٧	1
eSie™ Touch elasticity imaging	7		1	٧	1	V	1
syngo ® Auto Left heart	٧.		1	1	٧	٧	4
syngo ® Velocity Vector Imaging	7	٧	<b>V</b>	1	٧	4	V
Semi Auto-segmentation (eSie Calc)	٧ .	1	4	4	4	4	1
Custom Tissue Imaging / Speed of Sound	4		4	٧	4	4	٧
AHP	1	<u> </u>	1	7	٧	1	1
eSie Fusion (S3000 only)	7			<del></del>		٧	7

# S-Family Ultrasound Systems 510(k) Submission

Feature / Characteristic	Acuson S1000/S2000 /S3000 This Submission	Acuson SC2000 K123622	Acuson \$1000 K130619	Acuson \$2000 K112596	Acuson \$2000 K130739	Acuson \$3000 K121138	Acuson \$3000 K130739
<ul> <li>VTI (\$2000 &amp; \$3000 only)</li> </ul>	<b>V</b>	<del></del>			1		1
Wireless	7	4					
Monitor: 21° FPD	٧	7-	7	V	<b>V</b>	7	1
Output Display Standard (Track 3)	<b>√</b>	1	7	V	٧	7	1
Patient Contact Materials	Tested to ISO 10993-1	Tested to ISO 10993-1	Tested to ISO 10993-1	Tested to ISO 10993-1	Tested to ISO 10993-1	Tested to ISO 10993-1	Tested to ISC 10993-1
UL 60601-1 Certified		7	٧	√ √	4	1	4
Indications for Use	1	√		√	1	√	4

# 7. A brief discussion of nonclinical tests submitted, referenced, or relied on in the 510(k) for a determination of substantial equivalence.

The device has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical, electromagnetic and mechanical safety and has been found to conform with applicable medical device safety standards. The system complies with the following voluntary standards:

- UL 60601-1, Safety Requirements for Medical Equipment
- IEC 60601-2-37 Diagnostic Ultrasound Safety Standards
- CSA C22.2 No. 601-1, Safety Requirements for Medical Equipment
- AIUM/NEMA UD-3, Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
- AIUM/NEMA UD-2, Acoustic Output Measurement Standard for Diagnostic Ultrasound
- 93/42/EEC Medical Devices Directive
- Safety and EMC Requirements for Medical Equipment
  - EN/IEC 60601-1
  - EN/IEC 60601-1-1
  - EN/IEC 60601-1-2
- IEC 1157 Declaration of Acoustic Power
- ISO 10993-1 Biocompatibility

Cleared patient contact materials, electrical and mechanical safety are unchanged.

Additional testing was performed to verify the software release as well as transducer and wireless performance.

# 8. A summary discussion of the clinical tests submitted, referenced, or relied on for a determination of substantial equivalence.

Since the \$1000, \$2000, \$3000 systems use the same technology and principles as existing devices, clinical data is not required.

## 9. Summary

Intended uses and other key features are consistent with traditional clinical practice and FDA guidelines. The design and development process of the manufacturer conforms with 21 CFR 820 Quality System Regulation and ISO 13485:2003 quality system standards. The product is designed to conform to applicable medical device safety standards and compliance is verified through independent evaluation with ongoing factory surveillance. Diagnostic ultrasound has

accumulated a long history of safe and effective performance. Therefore it is the opinion

K132804 Page 5045

Siemens Medical Solutions, Inc. Ultrasound Division

S-Family Ultrasound Systems 510(k) Submission

of Siemens Medical that the S1000, S2000 and S3000 systems are substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.



Food and Drug Administration 10903 New Hampshire Avenue Document Control Center ≈ WO66-G609 Silver Spring, MD 20993-0002

October 24, 2013

Siemens Medical Solutions USA, Inc. % Mr. Mark Job Responsible Third Party Official Regulatory Technology Services LLC 1394 25<sup>th</sup> Street NW BUFFALO MN 55313

Re: K132804

Trade/Device Name: Acuson S1000/ S2000/ S3000<sup>™</sup> Diagnostic Ultrasound Systems

Regulation Number: 21 CFR 892.1550

Regulation Name: Ultrasonic pulsed doppler imaging system

Regulatory Class: 11

Product Code: IYN, IYO, ITX and OBJ

Dated: October 9, 2013 Received: October 10, 2013

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

This determination of substantial equivalence applies to the following transducers intended for use with the Acuson \$1000/\$2000/\$3000 Diagnostic Ultrasound System, as described in your premarket notification:

# Transducer Model Number

CW2	CW5	EC9-4
MC9-4	9L4	141.5
4P1	6C2	4C1
6C1HD	8C3HD	4V1
10V4	14L5 SP	7CF2
7CF1	9EVF4	V5Ms
18L6	8V3	4Vlc
6L3	EV8C4	V7M TEE
AcuNav 8F	AcuNav 10F	

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <a href="http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm">http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm</a>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris

Smh. 7)

Director, Division of Radiological Health

for

Office of In Vitro Diagnostics and Radiological Health

Center for Devices and Radiological Health

Enclosure

# S-Family Ultrasound Systems 510(k) Submission

#### 1.3 Indications for Use

A. 510(k) Number (if known): K132804

Device Name: \$1000, \$2000, \$3000 Diagnostic Ultrasound Systems

#### Indications for Use:

Proscription Use

The ultrasound imaging systems are intended for the following applications: Fetal, Abdominal, Intraoperative, Pediatric, Small Parts, Transcranial, OB/GYN, Cardiac, Pelvic, Neonatal/Adult Cephalic, Vascular, Musculoskeletal, Superficial Musculoskeletal, and Peripheral Vascular applications.

The system also provides the ability to measure anatomical structures {fetal, abdominal, intraoperative, pediatric, small organ, neonatal cephalic, adult cephalic, cardiac, trans-esophageal, transrectal, transvaginal, peripheral vessel, musculo-skeletal (conventional), musculo-skeletal (superficial) and neonatal cardiac} and calculation packages that provide information to the clinician that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes.

The Arterial Health Package (AHP) software provides the physician with the capability to measure Intima Media Thickness and the option to reference normative tables that have been validated and published in peer-reviewed studies. The information is intended to provide the physician with an easily understood tool for communicating with patients regarding state of their cardiovascular system. This feature should be utilized according to the "ASE Consensus Statement; Use of Carotid Ultrasound to Identify Subclinical Vascular Disease and Evaluate Cardiovascular Disease Risk: A Consensus Statement from the American Association of Echocardiography; Carotid Intima-Media Thickness Task Force, Endorsed by the Society for Vascular Imaging".

The Acuson Acunav Ultrasound Catheter is intended for intra-cardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology, as well as visualization of other devices in the heart of adult and pediatric patients.

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510(k)	K132804	_	Page 1 of	
Division Sig Division of I		fice of In Vitro Diagnostics	and Radiological Health	
Smir.7	7)	_		
	1	Office of In Vitro Diagnos	stics and Radiological Health (OIR)	
. (F	PLEASE DO NOT WI	RITE BELOW THIS LIN	E-CONTINUE ON ANOTHER PAGE IF NE	EDED)
,	R 801 Subpart D)		(21 CFR 801 Subpart C)	
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#### 1.3 Indications for Use Forms

## Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: Intended Use: ACUSON S1000, S2000, S3000 Ultrasound System

Ultrasound imaging or fluid flow analysis of the human body as follows:

Jse: L	Ultrasound imaging or fluid flow analysis of the human body as follows:  Mode of Operation									
Clinical Application	A	В	м	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										··· , · · · · · · · · · · · · · · · · ·
Fetal		Р	Р	Р	P	P	P		BMDC	Note 2,3,4,5,7,8,10, 11, 13
Abdominal		Ρ	Р	Р	Р	P	Р		BMDC	Note 2,3,4,5,7,8,10, 11, 13, 16, 18
Intraoperative (Note 9)		Р	Р	Р	₽	P	P		BMDC	Note 2,3,4,5,7,8,10, 11, 14
Intraoperative Neurological										
Pediatric		Р	Р	Р	Р	₽	Р		BMDC	Note 2,3,4,5,7,8,10, 11
Small Organ (Note 1)		P	Р	Р	Р	Ρ	Ρ		BMDC	Note 2,3,4,5,7,8,10, 11,14, 16, 18
Neonatal Cephalic		P	Р	Р	Р	Р	Р		вмос	Note 2,3,4,5,7,8,10
Adult Cephatic		Р	P	Р	Р	Р	Р		BMDC	Note 2,3,4,5,7,8,10
Cardiac		Р	P	Р	P	Р	Р		BMDC	Note 2,3,4,5,6,7,8,10,15
Trans-esophageal		Р	P	Р	Р	Р	þ		BMDC	Note 4
Transrectal		Р	Р	P		Р	p		BMDC	Note 2,3,4,5,7,8,10, 11,14
Transvaginal		Р	Р	Р		Р	P		BMDC	Note 2,3,4,5,7,8,10, 11
Transurethral										
Intravascular										
Peripheral vessel		Р	Р	Р	Р	P	Р		BMDC	Note2,3,4,5,6,7,8,10, 11,14,15
Laparoscopic										
Musculo-skeletal Conventional		Р	Р	Р	Ρ	<del>P</del>	Р		BMDC	Note 2,3,4,5,7,8,10, 11,14, 18
Musculo-skeletal Superficial		Р	Р	Р	Р	P	P		BMDC	Note 2,3,4,5,7,8,10, 11,14, 18
Other (specify) Neonatal Cardiac		Р	Р	Р	Р	Р	Р		BMDC	Note 3,4,6, 10

N = new indication. P = previously cleared by FDA K063085, K063803, K072786, K081148, K082142, K090334, K093812, K111674, K112596, K121138, K123001, K130619, K130735

Note 1	i e breast, testes, thyroid, penis, prostate, etc.	Note 2. Ensemble tissue harmonic imaging	Note 3 SieClear multi-view spatial compour
Note 4	Tissue Equalization Technology	Note 5 3-Scape real-time 3D imaging	Note 6. Cadence contrast agent imaging
Note 7	B&W SieScape panoramic imaging	Note 8: Power SieScape panoramic imaging	Note 9 For example vascular, abdominal
Note 10	Clarify VE vascular enhancement technology	Note 11 Advanced Sieclear spatial compounding	Note 13 STIC
Note 14	eSie ** Touch elasticity imaging / FTI	Note 15 AHP	Note 16 Custom Tissue Imaging

Note 14 eSie" Touch elasticity imaging / FTI

Note 17 Note 18 e\$ie Fusion VTI

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Division Sign-Off		
Division of Radiological Health; Office of In Vitro Diagnostics and Radiological Health		
510(k)	Page 2 of	

510 (k) Number (if known):

Device Name: Intended Use: CW2 Probe For Use On ACUSON \$1000, \$2000, \$3000 Ultrasound System

Ultrasound imaging or fluid flow analysis of the human body as follows

se: U	iiraso	una ii	magin	ig or flu	ia now a		the human	<del></del>	ROWS:	
	Mode of Operation									
Clinical Application	A	8	м	PWD	CWD	Calor Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal					Р					
Abdominal					Р					
Intraoperative (Note 9)					Р					
Intraoperative Neurological										
Pediatric					Р					
Small Organ (Note 1)					P					
Neonatal Cephalic					P					
Adult Cephalic					P				Ĺ	
Cardiac					Р					
Trans-esophageal		Ĺ	<u> </u>							
Transrectai										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel					Р					
Laparoscopic										•
Musculo-skeletal Conventional					P					
Musculo-skeletal Superficial					P					
Other (specify)										

N = new indication: P = previously cleared by FDA K# 063803, K072786, K081148, K082142, K090334, , K093812, K111674, k121138

Additional	Comments

Note 1	For example, breast,	testes, thyroid,	penis,	prostate, e	etc.
--------	----------------------	------------------	--------	-------------	------

Note 9 For example: vascular, abdominal

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Division Sign-Off	
Division of Radiological Health; Office of In Vitro Diagnostics and Radiological Health	
510(k)	Page 3 of

510 (k) Number (if known):

Device Name: Intended Use:

CW5 Probe For Use On ACUSON \$1000, \$2000, \$3000 Ultrasound System

Ultrasound imaging or fluid flow analysis of the human body as follows

						M	ode of Opera	ation		
Clinical Application	А	В	М	PWD	CWD	Calor Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ι						l]			
Fetal					Б					
Abdominal					Р					
Intraoperative (Note 9)					Ъ					
Intraoperative Neurological					Р					
Pediatric					Р				•	
Small Organ (Note 1)					Р					
Neonatal Cephalic					Р					
Adult Cephalic					Р					
Cardiac					Р					
Trans-esophageal										
Transrectal										
Transvaginal	-								1	
Transurethral										
Intravascular										
Peripheral vessel					Р					
Laparoscopic	$L^{-}$									
Musculo-skeletal Conventional					P					
Musculo-skeletal Superficial					Р					
Other (specify)										•

N = new indication; P = previously cleared by FDA K# 063803, K072786, K081148, K082142, K090334, , K093812, K111674, K121138

Additional	Comments:	

Note	1	For	example:	breast,	testes,	thyroid.	penis,	prostate,	etc.

Note 9 For example, vascular, abdominal

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Division Sign-Off		
Division of Radiological Health; Office of In Vitro Diagnost	ics and Radiological Health	
510(k)	•	Page 4 of

510 (k) Number (if known):

Device Name:

EC9-4 Curved Array Transducer For Use On ACUSON S1000, S2000, S3000

Ultrasound System

Intended Us

fluid flow analysis of the human bady as folk

d Use:	Ultra	soun	d ima	ging or	fluid flo	w analysis	of the hum	an body as	s foltows:	
							Mode of Op	peration		•
Clinical Application	А	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic		[	L							
Fetaf	<u> </u>	Р	Р	Р		Գ	Р		BMDC	Note 2,3,4,5,7,8,10, 11
Abdominal	L	Р	Р	Р		Р.	P		BMDC	Note 2,3,4,5,6,,7,8,10, 11,
Intraoperative	l .	L	L							
Intraoperative Neurological										
Pediatric										
Small Organ (Note 1)		Р	Р	Р		р	Р	-	BMDC	Note 2,3,4,5,7,8,10, 11,14
Neonatal Cephalic	1	P	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,10, 11
Adult Cephalic		L								
Cardiac	<u> </u>									
Trans-esophageal										
Transrectal		Р	Р	Р		Ρ	P		BMDC	Note 2,3,4,5, 6, 7,8,10, 11,14
Transvaginal		Р	Р	P		Р	P		BMDC	Note 2,3,4,5,7,8,10, 11
Transurethral										
Intravascular	L									
Peripheral vessel	<u></u>									_
Laparoscopic	L		L							
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)	<u> </u>									

N = new indication; P = previously cleared by FDA K# 063803, K072786, K081148, K082142, K090334, K093812, K111674, K121138

#### Additional Comments:

- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
- Ensemble tissue harmonic imaging Note 2
- Note 3 SieCtear multi-view spatial compounding
- Note 4 Tissue Equalization Technology
- Note 5 3-Scape real-time 3D imaging
- Note 6 Cadence contrast agent imaging Note 7 B&W SieScape panoramic imagin
- **B&W SieScape panoramic imaging**
- Note 8 Power SieScape panoramic imaging Note 10 Clarify VE vascular enhancement technology
- Note 11 Advanced Sieclear spatial compounding
- Note 14 eSie™ Touch elasticity imaging / FTt

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Division Sign-Off	
Division of Radiological Health; Office of In Vitro Diagnostics and Radiological Health	
510(k)	Page 5 of
	•

510 (k) Number (if known):

Device Name:

MC9-4 Curved Array Transducer For Use On ACUSON \$1000, \$2000, \$3000

Ultrasound Systems

Intended Use

d Use:	Ultra	soun	d ima	ging or	fluid flo	w analysis	of the hum	an body a:	s follows:	
							Mode of Op	eration		
Clinical Application	Α	В	м	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		N	N:	[ N	-	N	N		вмос	Note 2,3,4,5,7,8,10, 11
Abdominal	<u> </u>	N	N	N		2	N		BMDC	Note 2.3,4.5,6,,7,8,10, 11,
Intraoperative Note 9										
Intraoperative Neurological										
Pediatric										
Small Organ (Note 1)		N	N	N		N	N		BMDC	Note 2,3,4,5,7,8,10, 11,14
Neonatal Cephalic		N	N	N		N	N		BMDC	Note 2,3,4,5,7,8,10
Adult Cephalic			Ī							
Cardiac		L	l .	l .						
Trans-esophageal	]			]						
Transrectal		N	N	N		N	N		BMDC	Note 2,3,4,5, 6, 7,8,10, 11,14
Transvaginal		N	N	N		N	N		BMDC	Note 2,3,4,5,7,8,10, 11
Transurethral										
Intravascular										•
Peripheral vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)			_			-				

N = new indication; P = previously cleared by FDA K# 063803, K072786, K081148, K082142, K090334, K093812, K111674, K121138, K123001

## Additional Comments:

- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
  Note 2 Ensemble tissue harmonic imaging
- Ensemble tissue harmonic imaging
- SieClear multi-view spatial compounding
- Note 3 SieClear multi-view spatial comp Note 4 Tissue Equalization Technology
- Note 5 3-Scape real-time 3D imaging
- Note 6 Cadence contrast agent imaging Note 7 B&W SieScape panoramic imaging
- Note 8 Power SieScape panoramic imaging Note 9 Abdomen and Vascular
- Note 10 Clarify VE vascular enhancement technology
- Note 11 Advanced Sieclear spatial compounding
- Note 14 eSie™ Touch elasticity imaging / FTI

510(k)	Division Sign-Off Division of Radiological Health, Office of In Vitro Diagnostics and Radiological Health 510(k)	Page 6 of
	510(k)	

510 (k) Number (if known):

Device Name:

9L4 Linear Array Transducer For Use On ACUSON \$1000, \$2000, \$3000

Ultrasound Systems

Intended Use:

er fluid flavo analysis of the human hady on fallows:

ed Use:	Uitr	asou	nd im	aging o	r fluid fl	ow analysi	s of the hun	nan body a	as follows:	
1.							Mode of C	peration		
Clinical Application	А	8	м	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										·
Fetal		Р	Ρ	Р		Ρ	P		BMDC	Note 2,3,4,5,7,8,10, 11
Abdominal										
Intraoperative Note 9										
Intraoperative Neurological										
Pediatric		Р	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,10, 11
Small Organ (Note 1)		Р	Ρ	Р		Р	Р		BMDC	Note 2,3,4,5,6,7,8,10, 11,14, 16, 18
Neonatal Cephalic		Р	Р	P		Ρ	Р		BMDC	Note 2,3,4,5,7,8,10, 11
Adult Cephalic		Р	Р	P		Р	Р			
Cardiac		Ρ	Р	Р		Р	Р		BMDC	Note 15
Trans-esophageal										
Transrectal									_	
Transvaginal										
Transurethral		<u> </u>								
Intravascular										
Peripheral vessel		P	Р	P		Р	Р		BMDC	Note 2,3,4,5,6, 7,8,10, 11, 14,15
Laparoscopic										•
Musculo-skeletal Conventional		Р	Р	Р		Р	Р		вмос	Note 2,3,4,5,6,7,8,10, 11, 14
Musculo-skeletal Superficial		Р	Р	Р		P.	Р	·	BMDC	Note 2,3,4,5,6,7,8,10, 11, 14
Other (specify)										

N = new indication; P = previously cleared by FDA K# 063085, K072786, K081148, K082142, K090334, K093812, K111674, K121138, K130739

Additional Comments:
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Note 1	For example: breast,	testes, thyroid	, penis.	prostate.	etc

Note 3 SieClear multi-view spatial compounding 3-Scape real-time 3D imaging Note 5

Note 7 B&W SieScape panoramic imaging

Note 9 Abdomen and Vascular

Note 11 Advanced Sieclear spatial compounding

Note 15 AHP

Note 18 VTI (Virtual Touch Imaging)

Note 2	Ensemble tissue harmon	ic imaging

Tissue Equalization Technology Note 4

Note 6 Cadence contrast agent imaging Note 8 Power SieScape panoramic imaging

Note 10 Clarify VE vascular enhancement technology Note 14 eSie™ Touch elasticity imaging / FTI

Note 16 Custom Tissue Imaging

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Division Sign-Off Division of Radiological Health; Office of In Vitro Diagnostics and Radiological Health	
510(k)	Page 6 of

510 (k) Number (if known):

Device Name:

14L5 Multi-D Array Transducer For Use On ACUSON S1000, S2000, S3000 Ultrasound Systems
Ultrasound imaging or fluid flow analysis of the human body as follows:

Intended Use:

Use: L	ntraso	trasound imaging or fluid flow analysis of the human body as follows:								
		Mode of Operation								
Clinical Application	А	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal							-			
Abdominal				<u>.</u>						
Intraoperative Note 9										
Intraoperative Neurological										
Pediatric										
Small Organ (Note 1)		Р	Р	Р		<u>a</u>	P		BMDC	Note 2,3,4,5,7,8,10, 11, 14, 16
Neonatal Cephalic										
Adult Cephalic	L									
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral	<u>L.</u> _		<u> </u>							
Intravascular										
Peripheral vessel		Р	Р	Р		Р	Р	*	8MDC	Note 2,3,4,5,6, 7,8,10, 11, 14
Laparoscopic										
Musculo-skeletal Conventional		Р	Ρ	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,10, 11, 14
Musculo-skeletal Superficial										
Other (specify)										

	Other (specify)	<u> </u>			<u> </u>							
N = new	indication; P = previously	cleared by F	DA K#	063085	, K0727	36, K081148	, K082142, I	<09033	4. K(	93812, K11	1674, K121138	
Additional Note 1 Note 3 Note 5 Note 7 Note 9 Note 11 Note 16	al Comments: For example: breast, test SieClear multi-view spatia 3-Scape real-time 3D ima 8&W SieScape panoram Abdomen and Vascular Advanced Sieclear spatia Custom Tissue Imaging	at compound ging c imaging	ing	orostate,	etc.		Not	e 4 7 e 6 0 e 8 F e 10 0 e 14 e	Fissue Cader Power Clarify Sie **	e Equalization nce contrast : SieScape ; : VE vascula	narmonic imaging on Technology agent imaging panoramic imaging or enhancement te sticity imaging / FT	chnology
(PLEASE DO NOT WRITE BELOW THIS LINE-CON						HS LINE CON						
		·									•	
	•	Concurrent	e of C	DRH, O	ffice of t	n Vitro Diagn	iostics and F	Radiolog	gical I	Health (OIR)	)	
			•									
Division	Sign-Off Division of Radiok	gical Health	Office	e of In V	itro Diag	nostics and I	Radiological	Health				
510(k)	<del></del>									Page 7 o	ıf	

510 (k) Number (if known):

Device Name:

4P1 Phased Array Transducer For Use On ACUSON \$1000, \$2000, \$3000

Intended Us

Ultrasound Systems

j l	Jse:	Ultrase	Itrasound imaging or fluid flow analysis of the human body as follows:									
			Mode of Operation									
	Clinical Application	A	В	м	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)	
	Ophthalmic											
	Fetal		P	Р	Р	Р	Р	Р		BMDC	Note 2,3,4,5,7,8,10	
	Abdominal		Р	Р	P	P	Р	Ρ		BMDC	Note 2,3,4,5,7,8,10	
	Intraoperative Note 9						1					
	Intraoperative Neurological											
	Pediatric											
	Small Organ											
	Neonatal Cephalic	1										
	Adult Cephalic		Р	Р	Р	Р	₽	P		BMDC	Note 2.3,4,5,7,8,10	
	Cardiac	T	P	Ρ	P	Р	Р	P		BMDC	Note 2,3,4,5,6,7,8,10	
	Trans-esophageal	1			·			ĺ				
	Transrectal											
	Transvaginal											
	Transurethral											
	Intravascular								_			
	Peripheral vessel											
	Laparoscopic											
	Musculo-skeletal Conventional											
	Musculo-skeletal Superficial											
	Other (specify)											

N = new indication; P = previously cleared by FDA K# 063803, K072786, K081148, K082142, K090334, K093812, K111674, K121138

Additional Comments:		
	_	

Note 2	Ensemble tissue harmonic imaging
Note 3	SieClear multi-view spatial compounding
Note 4	Tissue Equalization Technology
Note 5	3-Scape real-time 3D imaging
Note 6	Cadence contrast agent imaging
Note 7	B&W SieScape panoramic imaging
Note 8	Power SieScape panoramic imaging
Note 9	Abdomen and Vascular

Note 10 Clarify VE vascular enhancement technology

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Division Sign-Off Division of Radiological Health; Office of In Vitro Diagnostics and Radiological Health	
510(k)	Page 8 of

510 (k) Number (if known):

Device Name:

6C2 Curved Array Transducer For Use On ACUSON \$1000, \$2000, \$3000

**Ultrasound Systems**'

Ultrasound imaging or fluid flow analysis of the human body as follows: Intended Use:

Use: L	ntrasc	ouna i	magır	ig or ilu	NO HOW	anaiysis oi	the human	oody as it	ilows:	
		Mode of Operation								
Clinical Application	А	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic					L					
Fetal		Р	Р	₽		P	Р		вмос	Note 2,3,4,5,7,8,10, 11
Abdominal		Р	Р	Р		Р	₽		BMDC	Note 2,3,4,5,7,8,10, 11, 14, 16, 17
Intraoperative Note 9										
Intraoperative Neurological										
Pediatric		Р	Р	Р		P	P		BMDC	Note 2,3,4,5,7,8,10, 11
Small Organ										
Neonatal Cephalic								·		
Adult Cephalic	Ĭ .									
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal								_		
Transurethral	Ī									_
Intravascular				L						·
Peripheral vessel		Р	Р	þ		Р	p		BMDC	Note 2,3,4,5,7.8,10,
Laparoscopic										-
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA K# 063085, K072786, K081148, K082142, K090334, K093812, K111674, K121138

Additiona	il Comments:
Note 2	Ensemble tissue harmonic imaging

Note 4 Tissue Equalization Technology

Note 7 B&W SieScape panoramic imaging

Note 9 Abdomen and Vascular

Note 11 Advanced Sieclear spatial compounding

Note 16 Custom Tissue Imaging

Note 3 SieClear multi-view spatial compounding

Note 5 3-Scape real-time 3D imaging

Note 8 Power SieScape panoramic imaging

Note 10 Clarify VE vascular enhancement technology Note 14 eSie™ Touch elasticity imaging / FTI

Note 17 eSie Fusion

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Division Sign-Off Division of Radiological Health; Office of In Vitro Diagnostics and Radiological Health	
510(k)	Page 9 of

510 (k) Number (if known):

Device Name:

4C1 Curved Array Transducer For Use On ACUSON S1000, S2000, S3000

**Ultrasound Systems** 

Intended Use:

Ultrasound imaging or fluid flow analysis of the human body as follows:

Use:	Ultras	Iltrasound imaging or fluid flow analysis of the human body as follows:											
		Mode of Operation											
Clinical Application	A	В	м	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)			
Ophthalmic					L								
Fetal		P	P	Р	Р	Ρ	Р		BMDC	Note 2,3,4,5,7,8,10, 11			
Abdominal		₽	Р	Р	Р	P	Р		BMDC	Note2,3,4,5.6,7,8, 10, 11, 14, 16, 17, 18			
Intraoperative Note 9													
Intraoperative Neurological													
Pediatric													
Small Organ		Р	Р	Р	₽	Р	Р		BMDC				
Neonatal Cephalic			<u> </u>				<u> </u>						
Adult Cepnalic													
Cardiac		Р	P	Р	P	Р	Ρ		BMDC				
Trans-esophageal													
Transrectal			L						[				
Transvaginal													
Transurethral													
Intravascular													
Peripheral vessel		Р	₽	Р	P	P	Р		BMDC				
Laparoscopic													
Musculo-skeletal Conventional										•			
Musculo-skeletai Superficial													
Other (specify)													

N = new indication; P = previously cleared by FDA K# 063085, K072786, K081148, K082142, K090334, K093812, K111674, K121138, K130739 Additional Comments:

Note 2	Ensemble tissue harmonic imaging	Note 3 SieCie	ear multi-view spatial compounding
Note 4	Tissue Equalization Technology		pe real-time 3D imaging
Note 6	Cadence contrast agent imaging	Note 7 B&W	SieScape panoramic imaging
Note 8	Power SieScape panoramic imaging	Note 9 Abdome	n and Vascular
Note 10	Clarify VE vascular enhancement technology	Note 11 Advar	nced Sieclear spatial compounding
Note 14	eSie™ Touch elasticity imaging / FTI	Note 16 Custo	m Tissue Imaging
Note 17	eSie Fusion	Note 18 VTI	

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Division Sign-Off Division of Radiological Health; Office of In Vitro Diagnostics and Radiological Health	
510 <sub>(k)</sub>	Page 10 of

510 (k) Number (if known):

Device Name:

6C1HD Curved Array Transducer For Use On ACUSON S2000, S3000 Ultrasound

Intended Us

۲	lse: U	Ultrasound imaging or fluid flow analysis of the human body as follows:										
ı			Mode of Operation									
	Clinical Application	А	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)	
	Ophthalmic			[			_					
	Fetal		Р	Р	Р	Р	Ρ	Р		BMDC	Note 2,3,4,5,7,8,10, 11	
	Abdominal		Р	Р	P	Ą	P	P		вмос	Note2,3,4.5,6,7,8, 10, 11, 14, 16, 17, 18	
	Intraoperative Note 9											
	Intraoperative Neurological		•									
ı	Pediatric											
1	Small Organ		Р	Ρ	Р	P.	Р	Р		BMDC		
ı	Neonatal Cephalic											
	Adult Cephalic											
Ì	Cardiac		Р	٩	Þ	Р	Р	Р		BMDC		
1	Trans-esophageal											
	Transrectal											
	Transvaginal								,	_		
	Transurethral											
ı	Intravascular							•				
	Peripheral vessel		Р	Р	P	Р	Ρ	Р		BMDC		
١	Laparoscopic											
	Musculo-skeletal Conventional											
	Musculo-skeletal Superficial											
	Other (specify)											

N = new indication; P = previously cleared by FDA K# 111674, K121138, K130739

## Additional Comments:

Note 4 Note 6 Note 8 Note 10 Note 14	Ensemble tissue harmonic imaging Tissue Equalization Technology Cadence contrast agent imaging Power SieScape panoramic imaging Clarify VE vascular enhancement technology eSie™ Touch elasticity imaging / FTI eSie Fusion	Note 5 Note 7 Note 9 Note 11	SieClear multi-view spatial compoundin 3-Scape real-time 3D imaging B&W SieScape panoramic imaging Abdomen and Vascular Advanced Sieclear spatial compounding Custom Tissue Imaging VTI
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Division Sign-Off Division of Radiological Health; Office of In Vitro Diagnostics and Radiological Health	
510(k)	Page 11 of

510 (k) Number (if known):

Device Name:

8C3HD Curved Array Transducer For Use On ACUSON \$2000, \$3000 Ultrasound

Systems

Intended Use:

Ultrasound imaging or fluid flow analysis of the human body as follows:

Jse: U	ntrasc	trasound imaging or fluid flow analysis of the human body as follows:									
		Mode of Operation									
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)	
Ophthalmic											
Fetal		P	Р	P		Р	Р		вмос	Note 2,3,4,5,7,8,10.	
Abdominal		Р	Р	Р		P	Р		вмос	Note 2,3,4,5,7,8,10, 11, 14, 16	
Intraoperative Note 9										•	
Intraoperative Neurological											
Pediatric		Þ	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,10,	
Small Organ		Р	₽	Р		Р	Р		BMDC		
Neonatal Cephalic										•	
Adult Cephalic									]		
Cardiac											
Trans-esophageal					[						
Transrectal											
Transvaginal		Γ									
Transurethral											
Intravascular				ļ							
Peripheral vessel		Р	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,10, 11	
Laparoscopic	I						L				
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											

N = new indication: P = previously cleared by FDA K#121138, K#130739

Additi	ional	Com	men	ts

Note 2	Ensemble tissue harmonic imaging	Note 3	SieClear multi-view spatial compounding
Note 4	Tissue Equalization Technology	Note 5	3-Scape real-time 3D imaging
Note 6	Cadence contrast agent imaging	Note 7	B&W SieScape panoramic imaging
Note 8	Power SieScape panoramic imaging	Note 10	Clarify VE vascular enhancement technolog
Note 11	Advanced Sieclear spatial compounding	Note 14	eSie™ Touch efasticity imaging / FTI

Note 16 Custom Tissue Imaging

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Division Sign-Off Division of Radiological Health; Office of In Vitro Diagnostics and Radiological He	ealth
510(k)	Page 12 of

510 (k) Number (if known):

Device Name:

4V1 Phased Array Transducer For Use On ACUSON \$1000, \$2000, \$3000

Intended Use:

Ultrasound Systems

When the standard or fluid flow analysis of the human body as follows:

Use: U	Ultrasound imaging or fluid flow analysis of the human body as follows:									
	Mode of Operation									
Clinical Application	А	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		Ρ	P.	Р		P.	P		BMDC	Note 2.3,4,5,7,8,10
Abdominal		P	Ρ	P		P	Р		вмос	Note 2,3,4,5,7,8,10, 14, 16, 17
Intraoperative					-			-		
Intraoperative Neurological										
Pediatric										
Small Organ										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral								<u> </u>		
Intravascular										
Peripheral vessel										
Laparoscopic										
Musculo-skeletal Conventional		·								
Musculo-skeletal Superficial										
Other (specify)									<u> </u>	

N = new indication: P = previously cleared by FDA K# 063085, K072786, K081148, K082142, K090334, K093812, K111674, K121138

#### Additional Comments:

Note 4 Note 7 Note 10	Tissue Equalization Technology B&W SieScape panoramic imaging Clarify VE vascular enhancement technology	Note 5 Note 8	
Note 14	,		Advanced Sieclear spatial compounding Custom Tissue Imaging
	eSie Fusion	Note 10	Custom rissue imaging
NUC II		TE BELOW THIS L	INE-CONTINUE ON ANOTHER PAGE IF NEEDED)
	Concurrence of CDRH, Off	fice of In Vitro Dia	agnostics and Radiological Health (OIR)
Division S	Sign-Off Division of Radiological Health; Office of In Vit	ro Diagnostics ar	nd Radiological Health
510(k)			Page 13 of

510 (k) Number (if known):

Device Name:

10V4 Phased Array Transducer For Use On ACUSON \$1000, \$2000, \$3000

Ultrasound Systems

Intended Use:

Ultrasound imaging or fluid flow analysis of the human body as follows:

Jse:	1	Mode of Operation								
Clinical Application	Α	В	м	PWD	CWD	Calar Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic		]								·
Fetal		Р	Р	Р	P	Ρ	Р		BMDC	Note 2,3,4,5,7,8,10
Abdominal		P	Р	Р	Р	ρ	Р		BMDC	Note 2,3,4,5,7,8,10
Intraoperative							-			
Intraoperative Neurological										
Pediatric	I	Р	P	Р	Р	Р	Р		BMDC	Note 2,3,4,5,7,8,10
Small Organ										
Neonatal Cephalic		P	P	Р	Р	P	Р		BMDC	Note 2,3,4,5,7,8,10
Adult Cephalic	<u> </u>									
Cardiac	İ	Р	Р	Р	Р	Р	Р		BMDC	Note 3,4
Trans-esophageal										•
Transrectal										
Transvaginal										
Transurethraf		ĺ			_	·		•		•
Intravascular										
Peripheral vessel		Р	Р	Р	Р	P	Р		BMDC	Note 2,3,4,5,7,8,10
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)						_				

N = new indication; P = previously cleared by FDA K# 063085, K072786, K081148, K082142, K090334, K093812, K111674, K121138

Additional Comments:		_
	LegantibhA	Comments

Note 2	Ensemble	tissue	harmonic imaging	
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•	Concurrence of CDRH, Office of In Vitro Diagnostics and I	Radiological Health (OIR)
Division Sign-Off Division	of Radiological Health; Office of In Vitro Diagnostics and Radiological	! Health
510(k)	_	Page 14 of
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Note 3 SieClear multi view spatial compounding

Note 4 Tissue Equalization Technology

Note 5 3-Scape real-time 3D imaging

Note 7 B&W SieScape panoramic imaging Note 8 Power SieScape panoramic imaging

Note 10 Clarify VE vascular enhancement technology

510 (k) Number (if known):

Device Name:

14L5 SP Linear Array Transducer For Use On ACUSON \$1000, \$2000, \$3000

Ultrasound Systems

Indications For Use:		Diagnostic imaging or fluid flow analysis of the human body as follows:								
		Mode of Operation								
Clinical Application	А	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic		I	]	l						
Fetal										
Abdominal			1							
Intraoperative (Note 9)		Р	P	P		Р	Р		BMDC	Note 2,3,4,5,7,8,10,11
Intraoperative Neurological										
Pediatric										
Small Organ (Note 1)		Р	P	P		P.	Ф		BMDC	Note 2,3,4,5,7,8,10, 11,14, 16
Neonatal Cephalic										
Adult Cephalic										•
Cardiac		Р	P	Ρ		<u>a</u>	Р		BMDC	Note 15
Transesophageal										
Transrectat										:
Transvaginal										
Transurethral			<u> </u>					- '		
Intravascular			<u> </u>	ļ <u></u>						
Peripheral vessel		Р	Р	Р		Р	P		BMDC	Note2,3,4,5,6 ,7,8,10, 11,14,15
Laparoscopic										
Musculo-skeletal Conventional		P	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,10, 11,14
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA K# 063085, K072786, K081148, K082142, K090334, K093812, K111674, K121138

Additional	Comments:	
Additional	CONTINUENCS.	

Note 1 For example: breast, testes, thyroid, penis, prostate, et	Note 1	For example: b	preast, testes,	thyroid,	penis,	prostate.	etc
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SieClear multi-view spatial compounding Note 3 Note 5 3-Scape real-time 3D imaging

Note 7 B&W SieScape panoramic imaging

Note 9 For example: vascular, abdominal

Note 11 Advanced Sieclear spatial compounding

Note 15 AHP

Note 2 Ensemble tissue harmonic imaging

Note 4 Tissue Equalization Technology

Note 6 Cadence contrast agent imaging

Power SieScape panoramic imaging Note 8

Note 10 Clarify VE vascular enhancement technology

Note 14 eSie™ Touch elasticity imaging / FTI
Note 16 Custom Tissue Imaging

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Division Sign-Off Division of Radiological Health; Office of In Vitro Diagnostics and Radio	ological Health	
510(k)	•	Page 15 of

510 (k) Number (if known):

Device Name:

7CF2 Curved array mechanical 3D transducer For Use On ACUSON \$1000, \$2000, \$3000 Ultrasound Systems
Ultrasound imaging or fluid flow analysis of the human body as follows:

Intended Use:

<u>Use:</u> U	Itraso	rasound imaging or fluid flow analysis of the human body as follows:								
		Mode of Operation								
Ctinical Application	A	8	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		Р	₽	Р		P	Р		вмос	Note 2.3,4,5,7,8,10, 11,13
Abdominal		Р	Р	P		Ρ	Р		BMDC	Note 2,3,4,5,7,8,10, 11, 13
Intraoperative										
Intraoperative Neurological										
Pediatric	Ī									
Small Organ										
Neonatal Cephalic										
Adult Cephalic							·			
Cardiac										
Trans-escphageal										
Transrectal							, ,			
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel										
Laparoscopic	$\Box$									
Musculo-skeletai Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = new indication: P = previously cleared by FDA K# 063803, K072786, K081148, K082142, K090334, K093812, K111674, K121138

Note 2	Ensemble tissue harmonic imaging
Note 3	SieClear multi-view spatial compounding
Note 4	Tissue Equalization Technology
Note 5	3-Scape real-time 3D imaging
Note 7	B&W SieScape panoramic imaging
Note 8	Power SieScape panoramic imaging
Note 10	Clarify VE vascular enhancement technology
Note 11	Advanced Sieclear spatial compounding
Note 13	STIC

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Division Sign-Off Division of Radiological Health; Office of In Vitro Diagnostics and R	adiological Health
510(k)	Page 16 o/

510	(k) N	lumber :	(if known)

Device Name:

7CF1 Curved array mechanical 3D transducer For Use On ACUSON \$1000, \$2000,

\$3000 Ultrasound Systems

Intended Use

Use: U	<u>Iltraso</u>	und ir	nagin	ig or flu	id flow a	analysis of	the human	body as fo	llows:	
					-	Mo	ode of Opera	ation	-	-
Clinical Application	А	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Cotor Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic					[					
Fetal		N	N	N		N	N		BMDC	Note 2,3,4,5,7,8,10, 11,13
Abdominal		N	N	N		N	N		BMDC	Note 2,3,4,5,7,8,10, 11, 13
Intraoperative				Ì						
Intraoperative Neurological				-						
Pediatric							-			
Small Organ										
Neonatal Cephalic										
Adult Cephalic					} -					
Cardiac										
Trans-esophageal				ľ ——						-
Transrectal										
Transvaginal										
Transurethral		Ì								
Intravascular	L									
Peripheral vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA K# 063803, K072786, K081148, K082142, K090334, K093812, K111674, K121138 **Additional Comments:** 

Note 2	Ensemble	tissue	harmonic	imaging

Note 13 STIC

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Division Sign-Off Division of Radiological Health; Office of In Vitro Diagnostics and Radiological Health		•
510(k)	Page 16 of	

SieClear multi-view spatial compounding

Note 4 Tissue Equalization Technology

Note 5 3-Scape real-time 3D imaging Note 7

B&W SieScape panoramic imaging Note 8 Power SieScape panoramic imaging

Note 10 Clarify VE vascular enhancement technology

Note 11 Advanced Sieclear spatial compounding

510 (k) Number (if known):

Device Name:

9EVF4 Curved Array Transducer For Use On ACUSON \$1000, \$2000, \$3000

Ultrasound Systems

Intended Use:

Ultrasound imaging or fluid flow analysis of the human body as follows:

	L	Mode of Operation								
Clinical Application	A	8	м	PWD	CWD	Calor Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		Р	Р	Р		P	Р	•	вмос	Note 2,3,4,5,7,8, 10,11, 13
Abdominal								-	1	
Intraoperative		I								<u> </u>
Intraoperative Neurological										
Pediatric										
Small Organ										
Neonatal Cephalic		Р	P	Р		P	Р		BMDC	Note 2,3,4,5,7,8, 10,11
Adult Cephalic							1			
Cardiac										
Trans-esophageal										
Transrectal				Ĺ					!	
Transvaginal		Р	Р	Ъ		P	Þ		BMDC	Note 2.3,4,5,7,8, 10,11
Transurethral					-					
Intravascular										<u></u> ,
Peripheral vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial								-		
Other (specify)										

N = new indication: P = previously cleared by FDA K# 063603, K072786, K081148, K082142, K090334, K093812, K111674, K121138

Additional	Comments
	COMMISSIONS

Note 2 Ensemble tissue harmonic imaging

Note 3 SieClear multi-view spatial compounding

Note 4 Tissue Equalization Technology

Note 5 3-Scape real-time 3D imaging

Note 7 B&W SieScape panoramic imaging

Note 8 Power SieScape panoramic imaging

Note 10 Clarify VE vascular enhancement technology

Note 11 Advanced Sieclear spatial compounding

Note 13 STIC

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Division Sign-Off Division of Radiological Health; Office of In Vitro Diagnostics and Radiological Health	
510(k)	Page 17 of

5	n	/k)	Numb	er (if	known	١.

Device Name:

V5Ms Multiplane TEE Transducer For Use On ACUSON \$1000, \$2000, \$3000

Intended Use:

	Mode of Operation									
Clinical Application	А	В	М	PWD	CMD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										-
Fetal										
Abdominat										
Intraoperative										
Intraoperative Neurological										
Pediatric										
Small Organ										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal		P	Р	Р	Р	Þ	Р		BMDC	Note 4
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial						_				
Other (specify)										

N = new indication: P = previously cleared by FDA K# 063803, K072786, K081148, K082142, K090334, K093812, K111674, K121138

Additional Co Note 4 Tiss	mments: ue Equalization Technology
	(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
	Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)
Division Sign-	Off Division of Radiological Health; Office of In Vitro Diagnostics and Radiological Health
510(k)	Page 18 of

510	ď٤١	Number	(if known).	

Device Name:

18L6 HD Linear Array Transducer For Use On ACUSON \$1000, \$2000, \$3000

Ultrasound Systems

Intended

se: L	litrasc	ound i	magir	ng or flu	id flow	analysis of	the human	body as fo	ollows:	
	Mode of Operation									
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	1									
Fetal										
Abdominal										
Intraoperative	T									
Intraoperative Neurological										
Pediatric										
Smali Organ (Note 1)		Р	Р	Р		Р	Р		8MDC	Note 2,3,4,5,7,8,10 11,14, 16
Neonatal Cephalic	]								'	
Adult Cephalic		T								,
Cardiac		Р	Р	Р	l	Р	Р		BMDC	Note 15
Trans-esophageal										
Transrectal					<u> </u>				<u> </u>	
Transvaginal										
Transurethral		Ī								. :
Intravascular	l								_	
Peripheral vessel		Р	Р	Р		Р	р		BMDC	Note 2,3,4,5,7,8,10 11,14,15
Laparoscopic										
Musculo-skeletal Conventional		P	Р	P		Р	Р		8MDC	Note 2,3,4,5,7,8,10 11,14
Musculo-skeletal Superficial		P	Р	Р		P	P		BMDC	Note 2,3,4,5,7,8,10 11,14
Other (specify)										·

N = new indication; P = previously cleared by FDA K081148, K082142, K090334, K093812, K111674, K121138

Addition	al Comments:  For example: breast, testes, thyroid, penis, prostate, etc.		
	For example: breast testes thuroid penis prostate etc.		
Note 1	Tor example, breast, testes, triffold, perils, prostate, etc.	Note 15	AHP
Note 2	Ensemble tissue harmonic imaging	Note 16	Custom Tissue Imaging
Note 3	SieClear multi-view spatial compounding		
Note 4	Tissue Equalization Technology		
Note 5	3-Scape real-time 3D imaging		
Note 7	B&W SieScape panoramic imaging		
Note 8	Power SieScape panoramic imaging		
Note 10	Clarify VE vascular enhancement technology		
Note 11	Advanced Sieclear spatial compounding		
Note 14	eSie™ Touch elasticity imaging / FTI		
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	Concurrence of CDRH, Office of In Vit	ro Diagnostics a	and Radiological Health (OI

Division Sign-Off Division of Radiological Health; Office of In Vitro D	Diagnostics and Radiological Health
510(k)	Page 19 of

510 (k) Number (if known):

Device Name:

8V3 Phased Array Transducer For Use On ACUSON \$1000, \$2000, \$3000

**Uitrasound Systems** 

Intended Use:

Ultrasound imaging or fluid flow analysis of the human body as follows:

Mode of Operation										
Clinical Application	А	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	Ρ	Р	Р	Р	Р		BMDC	Note 2.3,4,5,7,8,10
Abdominal			<u> </u>							
Intraoperative										
Intraoperative Neurological						_				
Pediatric	<u> </u>	P	Ρ	Р	Р	P	Р		BMDC	Note 2,3,4,5,7,8,10
Small Organ							,			
Neonatal Cephalic		₽	Р	Р	Р	P	Р		BMDC	Note 2,3,4,5,7,8,10
Adult Cephalic										
Cardiac		Р	Р	Р	Р	Р	9		BMDC	Note 3,4,6
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular						-				
Peripheral vessel		L								
Laparoscopic										
Musculo-skeletal Conventional	_							-		
Musculo-skeletal Superficial										
Other (specify) Neonatal Cardiac		Р	Р	Р	Р	þ	4		BMDC	Note 3,4,6

N = new indication; P = previously cleared by FDA K# 063085, K072786, K081148, K082142, K090334, K093812, K111674, K121138

Additional	Comments
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Note 2	Ensemble tissue harmonic imaging
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Division Sign-Off Division of Radiological Health; Office of In Vitro Diagnostics and R	•
510(k)	Page 20 of

SieClear multi-view spatial compounding Tissue Equalization Technology Note 3 Note 4

<sup>3-</sup>Scape real-time 3D imaging Cadence contrast agent imaging Note 5

Note 6 B&W SieScape panoramic imaging Note 7

Power SieScape panoramic imaging

Note 10 Clarify VE vascular enhancement technology

510 (k) Number (if known):

Device Name:

4V1c Phased Array Transducer For Use On ACUSON \$1000, \$2000, \$3000

**Ultrasound Systems** 

Intended Use:

		Mode of Operation								
Clinical Application	А	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		Ρ	Р	Р	₽	P	. Р		BMDC	Note 2 3 4 5 7 8 10
Abdominal		Р	Р	Р	Р	P	Р		BMDC	Note 2 3 4 5 7 8 10
intraoperative	T	P	Р	Р	Þ	Р	Р		BMDC	Note 2 3 4 5 7 8 10
Intraoperative Neurological		Р	Р	Р	Р	Р	Р		BMDC	Note 2 3 4 5 7 8 10
Pediatric		Р	Р	Р	Р	Р	P		BMDC	Note 2 3 4 5 7 8 10
Small Organ										
Neonatal Cephalic										_
Adult Cephalic	İ	Р	P	P	Р	Р	₽		BMDC	Note 2 3 4 5 7 8 10
Cardiac		Р	Р	Р	Р	Р	Р		BMDC	Note 2 3 4 5 7 8 10 15
Trans-esophageal										
Transrectal										
Transvaginal	Ī									
Transurethral										
Intravascular										
Peripheral vessel		Р	Р	Р	Р	Р	Р		BMDC	Note 2 3 4 5 7 8 10 15
Laparoscopic						-				
Musculo-skeletał Conventional										
Musculo-skeletal Superficial										
Other (specify) Neonatal Cardiac		Р	Р	Ъ	Р	Р	Р		BMDC	Note 2 3 4 5 7 8 10

N = new indication, P = previously cleared by FDA K#'s 052410, 051139, 041319, 032114, 022567, 063085, K090334, K093812, K111674, K121138

			_	
Note 2	Ensemble	tissue	harmonic	imaging

Note 15 AHP

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Division Sign-Off Division of Radiological Health; Office of In Vitro Diagnostics and Radiological Health								
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510(k) Page 21 of								

Note 3 SieClear multi-view spatial compounding Note 4 Tissue Equatization Technology

Note 5 3-Scape real-time 3D imaging

Note 6 Cadence contrast agent imaging

Note 7 B&W SieScape panoramic imaging Note 8 Power SieScape panoramic imaging

Note 10 Clarify VE vascular enhancement technology

510 (k) Number (if known):

Device Name:

6L3 Transducer For Use On ACUSON \$1000, \$2000, \$3000 Ultrasound Systems

Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

		Mode of Operation								
Clinical Application	Α	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		Р	Р	Р	Р	P	P		BMDC	Note 2 3 4 5 7 8 10, 11
Abdominal										. <u> </u>
Intraoperative Note 9		Р	Р	Р	Р	Р	Р		BMDC	Note 2 3 4 5 7 8 10, 11
Intraoperative Neurological										
Pediatric										
Small Organ		Р	Р	Р	P	Р	Р		BMDC	Note 2 3 4 5 7 8 10, 1
Neonatal Cephalic										
Adult Cephalic								_		
Cardiac		Р	Р	Р	P	Р	P		BMDC	Note 2 3 4 5 7 8 10 15
Trans-esophageal										
Transrectal					L					
Transvaginal										
Transurethral				L					<u> </u>	
Intravascular				<b>.</b>						
Peripheral vessel		Р	Р	Р	Р	Р	р		BMDC	Note 2 3 4 5 7 8 10. 11 15
Laparoscopic										
Musculo-skeletal Conventional		P	Р	P	Р	Р	Р		BMDC	Note 2 3 4 5 7 8 10, 11
Musculo-skeletal Superficial		Р	Р	Р	Р	Р	Р		8MDC	Note 2 3 4 5 7 8 10.
Other (specify)										

N = new indication; P = previously cleared by FDA K#'s 052410, 051139, 041319, 032114, 022567, 002807, 973767, 063085, K090334, K093812, V10 -K111674, K121138

Additional	Comments:
	COMMICTAL.

Note 2 Ensemble tissue harmonic imaging

Tissue Equalization Technology Note 4

Note 6 Cadence contrast agent imaging Note 8 Power SieScape panoramic imaging

Note 11 Advanced Sieclear spatial compounding

Note 3 SieClear multi-view spatial compounding

Note 5 3-Scape real-time 3D imaging

Note 7 B&W SieScape panoramic imaging

Note 10 Clarify VE vascular enhancement technology

Note 15 AHP

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Division Sign-Off Division of Radiological Health, Office of In Vitro Diagnostics and Radiological Health	•	
510(k)		Page 22 of

510 (k) Number (if known):

Device Name:

EV8C4 Transducer For Use On ACUSON \$1000, \$2000, \$3000 Ultrasound

**Systems** 

Intended Use:

Ultrasound imaging or fluid flow analysis of the human body as follows:

se: (	Ultrasound imaging or fluid flow analysis of the human body as follows:									
		Mode of Operation								
Clinical Application	A	В	м	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		Р	Р	P	Р	Р	Р		BMDC	Note 2 3 4 5 7 8 10
Abdominal		P	Р	P	P	Ρ	P		BMDC	Note 2 3 4 5 7 8 10
Intraoperative									[	
Pediatric										
Small Organ										
Neonatal Cephalic										
Adult Cephalic										,
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal		Ρ	ρ	P	Р	Р	Р		BMDC	Note 2 3 4 5 6 7 8 10
Transurethral										
Intravascular										
Peripheral vessel										
Laparoscopic		[	I							
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA K#'s 052410, 051139, 041319, 032114, 022567, 002807, 973767, 063085, K090334, K093812, K111674, K121138

Additional	Comments

Note	: 2	Ensemble	tissue	harmonic	imaging
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Division Sign-Off Division of Radiological Health; Office of In Vitro Diagnostics and Radiological Health						
510(k)	Page 23 of					

Note 3 SieClear multi-view spatial compounding

Note 4 Tissue Equalization Technology

Note 5 3-Scape real-time 3D imaging

Note 6 Cadence contrast agent imaging

Note 7 B&W SieScape panoramic imaging Note 8 Power SieScape panoramic imaging

Note 10 Clarify VE vascular enhancement technology

510 (k) Number (if known):

Device Name:

V7M TEE Transducer For Use On ACUSON \$1000, \$2000, \$3000 Ultrasound

Intended Use:

Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	A	В	M	PWO	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify) *	Harmonic Imaging	Other (Specify)
Ophthalmic	İ						<del></del>				İ
Fetal	1	<u> </u>									· · · · · · · · · · · · · · · · · · ·
Abdomina!		Р	Р	P	Р	P	P		P	Р	Note 4
Intraoperative											
Intraoperative Neurological			٠.								-
Pediatric	i T	P	Р	Р	Р	Р	Р		P	Р	Note 4
Small Organ (specify)										j	
Neonatal Cephalic	Ī	$\top$				1				l	
Adult Cephalic	1					<u> </u>					
Cardiac	i	P	P	Р	Р	P	Р	Ĭ	Р	Р	Note 4
Trans-esophageal		P	Р	Р	Р	Р	Р		Р	Р	Note 4
Transrectal	Ī		[							ļ	<u> </u>
Transvaginal											
Transurethral			·					1			
Intravascular					-			1	_		
Peripheral Vessel	<u> </u>										
Laparoscopic							<del> </del>				
Musculo-skeletal (Conventional)	_	ļ									
Musculo-skeletal (Superficial)											
Other (specify)							<del>  -  </del>				

P=previously cleared by the FDA under premarket notifications #K052410, #K051139, #K041319, #K032114, and #K022567, K093812, K111674, K121138

## **Additional Comments:**

\*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Do B+Power Doppler, B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+Clarify VE

iina	imad	nic	harmo	tissue	Ensemble	Note 2
ı	ımaq	INC.	narmo	tissue	Ensemble	Note 2

Note 4 Tissue Equalization Technology Note 10 Clarify VE vascular enhancement technology

	Concurrence of CDRH, Office of In	Vitro Diagnostics and Radiological Health (OIR)
Division Sign-Off Divis	ion of Radiological Health; Office of th Vitro Diagn	nostics and Radiological Health
510(k)		Page 24 of

51	เก	ík۱	Num	iber	fif.	known	١

Device Name:

AcuNav 8F Ultrasound Catheter For Use On ACUSON \$1000, \$2000, \$3000

**Ultrasound Systems** 

Intended Use:

Catheter is intended for intra-cardiac and intraluminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other

devices in the heart of adult and pediatric patients.

	Mode of Operation										
Clinical Application	A	В	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify) *	Other: Harmonic Imaging	
Ophtalmic											
Fetal	$\top$										
Abdominal											
Intraoperative									i		
(Vascular)	_!		<u>L</u>		<u> </u>						
Intraoperative	7										
(Neurological)			Į .					Į			
Pediatric		Ρ	P	Р	P	P	P		Р		
Small Organ											
(Specify)**											
Neonatal Cephalic											
Adult Cephalic					<u> </u>						
Cardiac		P	P	Р	Р	Р	Ρ,		Р		
Trans-esophageal											
Transrectal											
Transvaginal			Ì.								
Transprethral	-1	ľ									
Intra-Luminal		P	P	Р	Р	Р	Р		P		
Peripheral Vessel											
Laparoscopic										·	
Musculo-skeletal											
Conventional			li		<u> </u>						
Musculo-skeletal											
Superficial											
Other (Intra-Cardiae)		Р	Р	Р	Р	Р	Р		Р		

P=Previously cleared by the FDA K992631, K033650, K042593, K071234, K093812, K111674, K121138

Ā	dd	iti	ion	яl	Ca	m	ne	nt	S

\*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Pwer Doppler,

## B+M+POWER DOPPLER, B+PWD+POWER DOPPLER, B+CWD+POWER DOPPLER

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Division Sign-Off Division of Radiological Health; Office of In Vitro Diagnostics and Radiological Health	
510(k)	Page 25 of

510 (k) Number (if known):

Device Name:

AcuNav 10F Ultrasound Catheter For Use On ACUSON \$1000, \$2000, \$3000

Ultrasound Systems

Intended Use:

Catheter is intended for intra-cardiac and intraluminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other

devices in the heart of adult and pediatric patients.

Clinical Application	Mode of Operation										
	A	В	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify) *	Other: Harmonic Imaging	
Ophtalmic	l	l									
Fetal		<u></u>	<u> </u>					_			
Abdominal					]			1		<u> </u>	
Intraoperative (Vascular)											
Intraoperative (Neurological)											
Pediatrie		Р	Р	Р	Р	Р	Р		Р		
Small Organ (Specify)**											
Neonatal Cephalic							·			l .	
Adult Cephalic					,						
Cardiae		P	P	Р	Р	Р	P		Р		
Trans-esophageal											
Transrectal											
Transvaginal											
Transurethral									ļ		
Intra-Luminal		P	P	P	Р	Р	P		P		
Peripheral Vessel											
Laparoscopic											
Musculo-skeletal											
Conventional									<u> </u>		
Musculo-skeletal									!		
Superficial		<u> </u>	<u>L</u> _								
Other (Intra-Cardiae)		P	Р	Р	P	Р	Р	<u> </u>	P_		

P=Previously cleared by the FDA K992631, K033650, K042593, K071234, K093812, K111674, K121138

Auditional Comments:	
*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color	_
Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler,	
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B+M+POWER DOPPLER, B+PWD+POWER DOPPLER, B+CWD+POWER DOPPLER

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Division Sign-Off Division of Radiological Health; Office of In Vitro Diagnostics and Radiological Health	
510(k)	Page 26 of